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response to the appeal, which shall constitute final agency action.

[68 FR 62369, Nov. 4, 2003]

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS ¹

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APPENDIX A TO PART 72—SELECT AGENTS

AUTHORITY: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

Source: 45 FR 48627, July 21, 1980, unless otherwise noted.

§ 72.1 Definitions.

As used in this part:

Biological product means a biological product prepared and manufactured in accordance with the provisions of 9 CFR parts 102–104 and 21 CFR parts 312 and 600–680 and which, in accordance with such provisions, may be shipped in interstate traffic.

Diagnostic specimen means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

Etiologic agent means a viable microorganism or its toxin which causes, or may cause, human disease.

Interstate traffic means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

§ 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

§ 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of §72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

BACTERIAL AGENTS

Acinetobacter calcoaceticus. Actinobacillus— all species. Actinomycetaceae— all members. Aeromonas hydrophila. Arachnia propionica. Arizona hinshawii— all serotypes. Bacillus anthracis Bacteroides spp Bartonella— all species. Bordetella— all species. Borrelia recurrentis, B. vincenti. Brucella— all species. Campylobacter (Vibrio) foetus, C. (Vibrio) ieiuni. Chlamydia psittaci, C. trachomatis. Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.

¹The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.